



PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

James Hunter Boone, et al.

Serial No. 10/656,034

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) Art Unit:

Filed: September 5, 2003

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) Examiner:

Title: Method for Distinguishing  
Ulcerative Colitis from  
Crohn's Disease by Detecting  
the Presence of Fecal Anti-  
Neutrophil Cytoplasmic  
Antibodies (ANCA)

)

) Attorney Docket: TLAB.100294

CERTIFICATE OF MAILING  
37 C.F.R. 1.8

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Jan Dickman

Signature

INFORMATION DISCLOSURE STATEMENT

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Dear Sir:

In compliance with Applicants duty of disclosure pursuant to 37 C.F.R. Section 1.56, it is requested that this Information Disclosure Statement be entered and that the references listed below and on the enclosed Form PTO-1449 be considered by the Examiner and made of record. Copies of the above-referenced documents are enclosed.

| U.S. PATENT NUMBER | ISSUE DATE       | INVENTOR       |
|--------------------|------------------|----------------|
| 5,359,038          | October 25, 1994 | Padron, Eloy   |
| 5,932,429          | August 3, 1999   | Targan, et al. |
| 5,968,741          | October 19, 1999 | Plevy, et al.  |
| 6,218,129          | April 17, 2001   | Walsh, et al.  |

**OTHER DOCUMENTS (Including Author, Title, Relevant Pages, and Place of Publication, Date)**

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|--|
| R. Barnes, S. Allan, C. Taylor-Robinson, R. Finn, P. Johnson, "Serum Antibodies Reactive with <i>Saccharomyces cerevisiae</i> in Inflammatory Bowel Disease: Is IgA Antibody a Marker for Crohn's Disease? " <i>Int Arch Allergy Appl Immunol</i> (1990) 92, 9-15.                                 |
| C. Faille, D. Mackenzie, J. Michalski, and D. Poulain, "Evaluation of an Enzyme Immunoassay Using Neoglycolipids Constructed from <i>Candida albicans</i> Oligomannosides to Define the Specificity of Anti-Mannan Antibodies" <i>Eur. J. Clin. Microbiol. Infect. Dis.</i> , (1992) May, 438-446. |
| M. Giaffer and C. Holdsworth, "Antibodies to <i>Saccharomyces cerevisiae</i> in patients with Crohn's disease and their possible pathogenic importance" <i>Gut</i> (1992) 33, 1071-1075.   |
| S. Hanauer, "Inflammatory Bowel Disease" <i>The New England Journal of Medicine</i> (1996) 334, 841-848.   |
| S. Hanauer and G. D'Haens, "Medical Management of Ulcerative Colitis" in Targan and Shanahan Inflammatory Bowel Disease: From Bench to Bedside, <i>Williams and Wilkens</i> (1994) 545-561.  |
| C. Jongeneel, L. Briant, I. Udalova, A. Sevin, S. Nedospasov, and A. Thomsen, "Extensive genetic polymorphism in the human tumor necrosis factor region and relation to extended HLA haplotypes" <i>Proc. Natl. Acad. Sci. USA</i> (1991) 88, 9717-9721.   |
| E. Lindberg, K. Magnusson, C. Tysk, and G. Jarnerot, "Antibody (IgG, IgA, and IgM) to baker's yeast <i>Saccharomyces cerevisiae</i> ), yeast mannan, gliadin, ovalbumin and betalactoglobulin in monozygotic twins with inflammatory bowel disease" <i>Gut</i> (1991) 909-913.                     |
| J. Main, H. McKenzie, G. Yeaman, M. Kerr, D. Robson, C. Pennington, and D. Parratt, "Antibody to <i>Saccharomyces cerevisiae</i> (bakers' yeast) in Crohn's disease" <i>BMJ</i> (1988) 297 1105-1106.  |
| H. McKenzie, J. Main, C. Pennington, and D. Parratt, "Antibody to selected strains of <i>Saccharomyces cerevisiae</i> (baker's and brewer's yeast) and <i>Candida albicans</i> in Crohn's disease" <i>Gut</i> (1990) 31, 537-538.  |

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| H. McKenzie, D. Parratt, J. Main, and C. Pennington, "Antigenic heterogeneity of strains of <i>Saccharomyces cerevisiae</i> and <i>Candida albicans</i> recognized by serum antibodies from patients with Crohn's disease" <i>FEMS Microbiology Immunology</i> (1992) 89, 219-224.   |
| H. Yang, J. Rotter, H. Toyoda, C. Landers, D. Tyan, C. McElree, and S. Targan, "Ulcerative Colitis: A Genetically Heterogeneous Disorder Defined by Genetic (HLA Class II) and Subclinical (Antineutrophil Cytoplasmic Antibodies) Markers" <i>The American Society for Clinical Investigation, Inc.</i> (1993) 92, 1080-1084. |
| C. Young, A. Sonnenberg, and E. Burns, "Lymphocyte Proliferation Response to Baker's Yeast in Crohn's Disease" <i>Digestion</i> (1994) 55, 40-43.  |
| M. Giaffer, A. Clark, C. Holdsworth, "Antibodies against <i>Saccharomyces Cerevisiae</i> (Baker's & Brewer's yeast) in Crohn's Disease" <i>Gastoreenterology</i> (1991) 100, No. 5, Part 2.  |
| G. Barclay, H. McKenzie, J. Pennington, D. Parratt, and C. Pennington, "The Effect of Dietary Yeast on the Activity of Stable Chronic Crohn's Disease" <i>Scand J Gastroenterol</i> (1992) 27, 196-200.  |
| M. Broker, H. Harthus, and R. Barnes, "A murine monoclonal antibody directed against a yeast cell wall glycoprotein antigen of the yeast genus <i>Saccharomyces</i> " <i>FEMS Microbiology Letters</i> (1994) 118, 297-304.  |
| C. Darroch, S. Christmas, and R. Barnes, " <i>In vitro</i> human lymphocyte proliferative responses to a glycoprotein of the yeast <i>Saccharomyces cerevisiae</i> " <i>Immunology Letters</i> (1994) 81, 247-252.   |
| B. Heelan, S. Allan, and R. Barnes, "Identification of a 200-kDa glycoprotein antigen of <i>Saccharomyces cerevisiae</i> " <i>Immunology Letters</i> (1991) 28, 181-186.   |
| C. Galperin and M. Gershwin, "Immunopathogenesis of Gastrointestinal and Hepatobiliary Diseases, <i>JAMA</i> , (1997) 278, 1946-1955.  |
| R. Barnes, S. Allan, C. Robinson, R. Finn, and P. Johnson, "Serum Antibodies Reactive with <i>Saccharomyces cerevisiae</i> in Inflammatory Bowel Disease: Is IgA Antibody a Marker for Crohn's Disease?" <i>Int. Arch. Allergy Appl. Immunol</i> (1990) 92, 9-15.  |
| J. Colombel, B. Sendid, J. Quinton, P. Jacquinot, O. Goulet, A. Cortot, D. Poulain, "Anti- <i>Saccharomyces cerevisiae</i> Antibodies: A New Subclinical Marker for Crohn's Disease" <i>Gastroenterology</i> (1996) 110, No. 4.  |
| N. Oshitani, et al., <u>IgG subclasses of anti <i>Saccharomyces cerevisiae</i> antibody in inflammatory bowel disease</u> ; Blackwell Science Ltd., European Journal of Clinical Investigation, Vol. 31, pp. 221-225, 2001.  |

**FOREIGN PATENT OR PUBLISHED FOREIGN PATENT APPLICATION**

| EXAMINER INITIAL | PUBLICATION NUMBER | PUBLICATION DATE | COUNTRY OR PATENT OFFICE | CLASS                 | SUBCLASS |
|------------------|--------------------|------------------|--------------------------|-----------------------|----------|
|                  | WO 99/60403        | 25 November 1999 | PCT                      | G01N 33/564, 33/569   |          |
|                  | WO 97/39356        | 23 October 1997  | PCT                      | G01N 33/564           |          |
|                  | WO 98/46997        | 22 October 1998  | PCT                      | G01N 33/53, C12Q 1/68 |          |
|                  | WO 01/11334 A2     | 15 February 2001 | PCT                      | G01N                  |          |

Respectfully submitted,



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Attorney Docket No. TLAB.100294

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PATENT

Serial No. 10/656,034

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| PTO-1449 (Modified)<br><br>U.S. DEPARTMENT OF COMMERCE<br>PATENT AND TRADEMARK OFFICE   |  | Attorney Docket No.:<br><br>TLAB.100294 | Serial Number: 10/656,034 |
| INFORMATION DISCLOSURE STATEMENT<br>BY APPLICANT  |  | Applicant: James Hunter Boone, et al.   |                           |
| Title: Method for Distinguishing Ulcerative Colitis from Crohn's Disease by Detecting the Presence of Fecal Anti-Neutrophil Cytoplasmic Antibodies (ANCA) |  | Filing Date: September 5, 2003          | Group:                    |

## U.S. PATENT DOCUMENTS

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|------------------|---------------|------------------|----------------|-------|----------|-------------|
|                  | 5,359,038     | October 25, 1994 | Padron, Eloy   |       |          |             |
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| S. Hanauer and G. D'Haens, "Medical Management of Ulcerative Colitis" in Targan and Shanahan <i>Inflammatory Bowel Disease: From Bench to Bedside</i> , <i>Williams and Wilkens</i> (1994) 545-561.   |
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|------------------|-----------------|------------------|--------------------------|-------|-----------------------|-------------|----|
|                  | WO 99/60403     | 11/25/1999       | PCT                      |       | G01N 33/564, 33/569   | YES         | NO |
|                  | WO 97/39356     | 10/23/1997       | PCT                      |       | G01N 33/564           |             |    |
|                  | WO 98/46997     | 10/22/1998       | PCT                      |       | G01N 33/53, C12Q 1/68 |             |    |
|                  | WO 01/11334 A2  | 02/15/2001       | PCT                      |       | G01N                  |             |    |
|                  |                 |                  |                          |       |                       |             |    |
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